UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

DAVID LOOMIS, et al.,	)	**CASE NO. 1:04CV0499**
	)	
Plaintiff,	)	**JUDGE CHRISTOPHER A. BOYKO**
	)	
Vs.	)	
	)	
MEDTRONIC, INC.,	)	**OPINION AND ORDER**
	)	
Defendant.	)	

CHRISTOPHER A. BOYKO, J:

This matter comes before the Court on Defendant's ("Medtronic") Motion for Summary Judgment. Upon careful consideration and review, the Court grants Defendant's Motion for Summary Judgment, as there are no genuine issues of fact and Defendant is entitled to judgment as a matter of law.

I. FACTUAL BACKGROUND

Plaintiffs, David and Jennifer Loomis, individually and on behalf of their minor child, Jacqueline Loomis, and Isome Redditt, Jr. and Mara Redditt, individually, and on behalf of their minor child, Racheal

Jackson, filed a complaint against Medtronic, Inc. alleging defective design, defective manufacture, failure to conform to representation, negligence, strict liability, breach of warranty, and loss of consortium claims relating to the minors' surgically implanted pacemakers which were replaced prematurely due to a recall. Plaintiffs allege that as a result of the surgeries to replace their recalled Medtronic Kappa 700/600 Implantable Pulse Generators ("Kappa IPG" or "pacemaker") they suffered economic loss, mental and physical pain, and continued mental anguish. Plaintiffs concede that the claims for statutory products liability, negligence, strict liability, and warranty claims are all preempted by federal law. Thus, only the manufacturing defect and underlying loss of consortium claims remain for consideration.

Medtronic, Inc. leased, sold, distributed, and supplied the Kappa IPG. In a letter dated March 15, 2002 ("Doctor Letter"), Medtronic informed doctors that it had observed failures of the Kappa pacemaker in patients having submuscular implants. The Kappa IPG had presented with failures of approximately 5% of submuscular implant locations. Medtronic identified the cause as fractured wires supplying power to the pacemaker. The submuscular implant locations resulted in additional stress and repetitive flexing on the pacemaker causing excessive fatigue on the wires. These failures were not observed in subcutaneous implants and the overall failure rate of the Kappa IPG is 0.02%. *Id*. Medtronic voluntarily provided this information to health care providers.

Plaintiffs were first advised of Medtronic's recall of the pacemakers in March, 2002 through their cardiac care providers at the Akron Children's Hospital in Akron, Ohio, which had originally implanted the pacemakers in each of the plaintiffs. Medtronic recommended that patients having submuscular implants of the pacemakers within the named serial number ranges who were pacemaker

dependent with no underlying rhythm consider replacement. Medtronic offered to provide a replacement device and honor its warranty obligations.

The FDA required Medtronic to obtain premarket approval (PMA) prior to marketing the Kappa IPG.[1] The FDA issued PMA for Medtronic's Kappa IPG, which authorized Medtronic to market the pacemaker in accordance with the approved specifications and prohibited any changes in the approved design, labeling, manufacturing, or construction methods that would affect safety or effectiveness of the device.

The Kappa IPG is subject to enhanced regulatory controls under the Good Manufacturing Practice Regulations. 21 C.F.R. Part 820. Medtronic had an internal quality assurance program, including written manufacturing specifications and procedures. It also utilized inspections to ensure that the Kappa IPG met all quality standards and that it conformed to Medtronic's application approved by the FDA. Medtronic submitted two employee affidavits stating that it manufactured the Kappa IPG, including the pacemakers at issue, in accordance with the specifications contained in Medtronic's PMA application.

II. STANDARD OF REVIEW

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (quoting Fed. R. Civ. P. 56(c)). A fact is genuine when it can

[1]The Kappa IPG is classified as a Class III medical device under 21 U.S.C. §360(f).

only be resolved "by a finder of fact because it may be reasonably be resolved in favor of either party." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 248 (1986). A fact is material when it "might affect the outcome of the suit under the governing law." *Id*. An opponent of a motion for summary judgment may not rely on the mere allegations of the complaint, but must set forth specific facts showing a genuine issue for trial. *Id.* No genuine issue exists for trial when no reasonable jury could return a verdict for the nonmoving party. *Id.* In evaluating a motion for summary judgment the court must evaluate all reasonable inferences from facts in the record in a light most favorable to the nonmoving party and must construe the evidence in favor of the nonmoving party. *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

III. LAW AND ANALYSIS

A. Preemption

The Supremacy Clause of the United States Constitution provides that the "Laws of the United States...Shall be the supreme Law of the Land." U.S. Const. Art. VI, cl. 2. "State law that conflicts with federal law is 'without effect.' " *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). Central to determining the question of preemption is divining Congress' intent. *Id*. at 517-18. Because of the important principles of federalism in areas of public health and safety, the states' police powers are not preempted by federal law unless Congress' intent to do so is clearly expressed. *Hillsborough County, Florida v. Automated Medical Labs., Inc.*, 471 U.S. 707, 713 (1985). Where Congress has included an express preemption provision in a statute a court may not look beyond it to consider implied preemption. Rather, "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not preempted." *Cipollone*, 505 U.S. at 517.

Surgically implanted pacemakers are regulated by the 1976 Medical Device Amendments (MDA) to the federal Food, Drug, and Cosmetic Act (FDCA) and other regulations promulgated by the U.S. Food and Drug Administration (FDA). The MDA §360k(a) expressly preempts any state "requirement...which is different from or in addition to, any requirement applicable under this Act to the device." This provision preempts state requirements when the FDA establishes specific regulations or there are other specific requirements applicable to the device under the FDCA. Plaintiffs' claims are preempted under the MDA if (1) The FDA has established specific counterpart regulations or other specific federal requirements; that are (2) applicable to a particular device, and (3) make state regulations different from, or in addition to, the specific FDA requirements. *Kemp v. Medtronic*, Inc., 231 F.3d 216, 224-225 (6th Cir. 2000).

i. **Device Specific Requirements**

State law claims are preempted when the federal requirements are applicable to the device in question and specific to that particular device. *Kemp*, 231 F.3d at 225. The threshold requirement is whether the federal statutory or regulatory requirement is applicable to the specific defect alleged. *Id*. If the federal requirement is inapplicable to the specific defect alleged, an award of damages under state common law is not a different or additional requirement. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 500 (1996).

Federal Law requires the FDA to approve certain medical devices prior to their marketing. The MDA classifies medical devices into three categories based on risk to the public. Class I devices present no unreasonable risk to the public and are subject only to minimal controls. Class II devices are potentially more harmful and are subject to special federal controls. Class III devices cannot be

classified under I or II and present either unreasonable risk to human life, are used to sustain human life, or are used to support human life. Class III devices require premarket approval (PMA), a thorough review process by the FDA before the device may be marketed. Federal Food, Drug, and Cosmetic Act, §513,et. seq. as amended 21 U.S.C. 360c(a)(1)(A)-(C) (2000). Among other information, the manufacturer must submit "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device." 21 U.S.C. §360e(c)(1)(C) (2000).

Because of the heightened specificity requirements for premarket approval of a Class III device the PMA process is considered a device specific regulation. *Kemp*, 231 F.3d at 226-27. In *Kemp* the court held that the Investigational Device Exemption ("IDE") process is a device specific requirement.[2] The *Kemp* court held that its IDE analysis comported with the Seventh Circuit's analysis that "PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards, and labeling and is specific to the product." *Id.* The Kappa IPG is a Class III medical device which required approval through the PMA process. Therefore, the FDA has established specific federal requirements applicable to the Kappa through the PMA process.

ii. "Different from" or "In Addition to" Federal Requirements

In order to survive preemption the manufacturing defect claim must parallel the federal claim, yet not impose different or additional requirements than the federal requirements. *Lohr*, 518 U.S. at

[2]The IDE is an alternate process of Class III medical device regulation applicable when a substantially equivalent device has already been approved through the PMA process. 21 U.S.C. § 360e(b)(1)(B).

495. The Supreme Court addressed whether the MDA preempts various common law tort claims. The Court held that "nothing in §360k denies a state the right to provide a traditional damages remedy for violations of common law duties when those duties parallel federal requirements." *Id.* The presence of a damages remedy does not impose different or additional requirements than the MDA. The Court reversed the Eleventh Circuit's holding that plaintiffs' manufacturing defect claims were preempted. The Court was not concerned that this type of common-law requirement "not specifically developed 'with respect to' medical devices" would impede specific federal requirements, the policy underlying MDA preemption. *Id*. at 472.

Courts have carved out an exception to the preemption laws. If a state tort claim parallels a federal requirement directly regulating a medical device relating to health and safety and the state requirement does not impose requirements different from or in addition to the federal requirements, the claim is not preempted. *Id*.; see also *Cupek v. Medtronic*, 405 F.3d 421, 422-23 (6th Cir. 2005) (state law claims consistent with federal requirements are not preempted). The Plaintiffs' manufacturing defect claim can only survive preemption if the manufacturing defect claims parallel the FDA requirements and Medtronic deviated from those requirements. Plaintiffs' manufacturing defect claim parallels the federal MDA requirements and does not impose requirements "different from" or "in addition to" the federal requirements. Therefore, Medtronic's motion for summary judgment on the ground of preemption is denied.

B. Manufacturing Defect

Medtronic also moves for summary judgment on the ground that Plaintiffs have provided inadequate support for their manufacturing defect claim. To establish a products liability claim for a

manufacturing defect the claimant must establish, by a preponderance of the evidence: (1) The product is defective in manufacture or construction; and (2) The defect was a proximate cause of the harm. Ohio Rev. Code Ann. § 2307.73 (2005). A product is defective in manufacture, "when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specification, formula, or performance standards." A product may be defective in manufacture or construction even though the manufacturer exercised all possible care. Ohio Rev. Code Ann. § 2307.74(A)(1-2) (2005). Consistent with the Rules of Evidence, the claimant may rely on circumstantial evidence or "other competent evidence that establishes, by a preponderance of the evidence, that the product in question was defective." § 2307.74(B).

Along with its motion for summary judgment Medtronic submits two affidavits of Medtronic employees stating Medtronic at all times complied with the FDA requirements concerning manufacturing processes. Portions of the affidavits point to internal control documents showing that Medtronic did not deviate from established manufacturing standards. Medtronic has therefore met its initial burden of production, and the burden shifts to the Plaintiffs.

The Plaintiffs have the burden of proving that the wires in the Kappa IPGs at issue frayed as a result of a manufacturing defect. Plaintiffs, however, have offered no evidence which contradicts Medtronic's employee affidavits or internal control documents that demonstrate the Kappa IPG was manufactured according to specifications. Although the Plaintiffs have presented a triable issue regarding the proximate cause of the harm, they have failed to show any genuine issue of material fact showing that Medtronic deviated from its manufacturing process to produce a materially defective IPG

(as opposed to manufacturing an IPG as the result of a flawed manufacturing process, which would be preempted). Therefore, Plaintiffs have failed to meet their burden.

Plaintiffs contend that the failure of the IPGs must have been caused by a manufacturing defect because there were a limited number of units affected, fractured power supply wires were the defect and cause of the failure and recall, the manufacturing process was modified after the recall, the pacemaker's warranty provisions were admittedly implicated, and "other" evidence create a genuine issue of material fact. They further contend that the defect is apparent from the Doctor Letter and the recall notice itself.

However, beyond these broad, conclusory statements, Plaintiffs offer no support for their allegations such as affidavits or expert testimony to support the claim that Medtronic failed to comply with the FDA requirements in manufacturing the Kappas at issue.

Plaintiffs argue that the recalled IPGs were within a limited sequence of serial numbers. Apparently, there was a list of affected serial numbers attached to the Doctor Letter, but Plaintiffs have not provided that list nor provided an explanation for its absence.

Plaintiffs also contend that because the manufacturing process was changed to remedy the Kappa IPG, a manufacturing defect must have been responsible for their failure. The original employee affidavit confirms that Medtronic complied at all times with FDA regulations concerning the manufacturing processes for the pacemakers at issue. Medtronic's supplemental employee affidavit establishes that the changes in the manufacturing process referred to in the Doctor Letter were made

with FDA approval. Claims that the failure of the pacemakers at issue resulted from a flaw in the manufacturing process approved by the FDA would be preempted by federal law.

In *Davenport v. Medtronic, Inc.*, 302 F. Supp.2d 419, 437 (E.D. Pa. 2004), the court granted defendant's motion for summary judgment because the plaintiff failed to provide sufficient factual basis for his claims. The expert reports "ma(d)e broad conclusory statements such as the 'IPGs implanted...should not malfunction as it did...unless these devices were defective.'" *Id.* The court found that these broad statements were insufficient evidence, holding that "even at this stage (plaintiff) and his expert cannot simply point to the malfunction itself to prove that the (l)eads were not manufactured in accordance with the FDA/PMA specifications." *Id*. at 438. The court granted summary judgment for the defendant because the plaintiff had provided insufficient evidence to support the claim that defendant Medtronic had failed to comply with FDA regulations.

Plaintiffs here have not submitted any evidence supporting the claim that the failure or recall was a result of Medtronic's failure to adhere to the FDA standards or the parallel state requirements. Plaintiffs offer no explanation of what the "other" factual issues are and have not sought additional time for discovery under Rule 56(f). Summary judgment must be granted if adequate time for discovery has passed and the nonmoving party has failed to establish each element of its case. *Celotex*, 477 U.S. at 325. The plaintiff is required to present evidence, even if the evidence is likely to be in the control of the defendant, as long as the plaintiff has been given the opportunity to conduct discovery. *Liberty Lobby, Inc.*, 477 U.S. at 257. Plaintiffs have failed to do so. Even accepting every inference in their favor Plaintiffs' do not present any genuine issue of fact. Plaintiffs have thus failed to meet their burden of proof for defective manufacture. Therefore, Medtronic is entitled to judgment as a matter of law.

C. Loss of Consortium

Plaintiffs' loss of consortium claim fails because loss of consortium claims are derivative actions which depend on the existence of a primary cause of action. *Gearing v. Nationwide Ins. Co.*, 76 Ohio St.3d 34, 40 (Ohio 1996) (holding parents' claim for loss of consortium is derivative of their daughters' claims). Because Plaintiffs have not sustained their burden of proof on the manufacturing defect claim, the loss of consortium claim fails. Because this Court grants Medtronic's motion for summary judgment on all of Plaintiffs' substantive claims, the derivative loss of consortium claim must also be decided as a matter of law in Medtronic's favor.

IV. CONCLUSION

For the reasons stated above, the Court grants Medtronic's Motion for Summary Judgment because Plaintiffs have not satisfied their burden of presenting any genuine issues of fact on the state manufacturing defect claim.

IT IS SO ORDERED.

8/01/05
Date

/s/ Christopher A. Boyko
CHRISTOPHER A. BOYKO
United States District Judge
(Signed original on file)